



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/675,952 09/29/00 BACH

P 5974.200-US

EXAMINER

HM22/0817

ELIAS J LAMBIRIS ESQ
NOVO NORDISK OF NORTH AMERICA INC
SUITE 6400
405 LEXINGTON AVENUE
NEW YORK NY 10174-6400

OZGA.B

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

08/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/675,952

Applicant(s)

BACH, POUL

Examiner

Brett T Ozga

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 26, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 11, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 26, drawn to compositions of enzyme containing granules, classified in class 426.
- II. Claims 11, 34 and 35 drawn to processes for preparing enzyme containing granules, classified in class 435, subclass 187.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be used to make without the specific ranges detailed in claims 1-10 and 26.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Elias Lambiris on July, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10 and 26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11, 34 and 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5, 10 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3-5 and 10 recite the broad recitations of no more than 1 mm, up to 30%, 20-100% and not more than 2.5, respectively, and the claims also recite 200-300 micrometers, up to 5%, no less than 95% and not more than 1, respectively, which are the narrower statements of the ranges/limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamel et al. (US 5230822).

The instant application claims an enzyme-containing granule comprising a core unit and a shell unit, wherein the core unit comprises the enzyme and is enclosed in a shell unit which is substantially enzyme-free, the ratio between the diameter of the granule and the diameter of the core unit being at least 2.5. Dependent claims further limit by having the core unit below 1000 micrometers, the relative mass up to 30% of the total, the enzyme content in the core unit from 20-100% and a homogeneously dispersed enzyme. The instant application claims a composition comprising the enzyme containing granules. The instant application also claims a structured core unit and an enzyme-containing granule further comprising a film layer around the core unit form components present in the shell unit.

Kamel et al. teach an enzyme-containing granule comprising a core unit and a shell unit, wherein the core unit comprises the enzyme and is enclosed in a shell unit which is substantially enzyme-free, the ratio between the diameter of the granule and the diameter of the core unit being at least 2.5. Kamel et al. also teach having the core unit below 1000 micrometers, the relative mass up to 30% of the total, the enzyme content in the core unit from 20-100% and a homogeneously dispersed enzyme. They teach a composition comprising the enzyme containing granules. Kamel et al. also teach a structure core unit. (See col. 3-4, example IX and col.9 line 61-col. 10 line 60.)

Claims 1-6, 9 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Herdeman (US 4707287)

Herdeman teaches an enzyme-containing granule comprising a core unit and a shell unit, wherein the core unit comprises the enzyme and is enclosed in a shell unit, which is substantially enzyme-free, the ratio between the diameter of the granule and the diameter of the core unit being at least 2.5. Herdeman also teaches having the core unit below 1000 micrometers, the relative mass up to 30% of the total, the enzyme content in the core unit from 20-100% and a homogeneously dispersed enzyme. He teaches a composition comprising the enzyme containing granules. Herdeman teaches an enzyme-containing granule further comprising a film layer around the core unit from components present in the shell unit. (See whole document.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamel et al. (US 5230822).

Kamel et al. teach an enzyme-containing granule comprising a core unit and a shell unit, wherein the core unit comprises the enzyme and is enclosed in a shell unit which is substantially enzyme-free, the ratio between the diameter of the granule and the diameter of the core unit being at least 2.5. Kamel et al. also teach having the core unit below 1000 micrometers, the relative mass up to 30% of the total, the enzyme content in the core unit from 20-100% and a homogeneously dispersed enzyme. They teach a composition comprising the enzyme containing granules. Kamel et al. also teach a structure core unit. (See col. 3-4, example IX and col.9 line 61-col. 10 line 60.)

Kamel et al. do not expressly teach an enzyme-containing granule wherein the granule is a co-granule comprising more than one type of enzyme. They also do not teach a granulated enzymatic product comprising a multiplicity of enzyme granules

Art Unit: 1651

wherein the enzyme core unite have a particle size distribution such that the ratio (D90-D10)/D50 is not more than 2.5.

It would have been prima facie obvious to person of ordinary skill in the art at the time the invention was made to modify the number of enzymes in the granule of Kamel et al. to attain the advantage of a more widely useful product in that more enzymes yield more potential applications. Thus, in view of the cited reference, the artisan of ordinary skill would have been motivated to have practiced the granules and composition as recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.



SANDRA E. SAUCIER
PRIMARY EXAMINER